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10/530,703	09/23/2005	Stephen Kerr	127272.00311	7745

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EXAMINER

ADAMS, AMANDA S

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 08/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	10/530,703		KERR, STEPHEN	
	Examiner		Art Unit	
	Amanda Adams		3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 1 recites the limitation "the lumen" in line 4 of the claim. There is insufficient antecedent basis for this limitation in the claim.
3. Claim 29 recites the limitation "said metal reinforcement" in line 1 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1, 2, 9-11, 15, 19, 23, 26, 27, 30- 33, and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Kan et al (US 6,497,651).
2. Regarding claims 1, 15, 19, 30, and 31, Kan et al disclose a dissector device comprising an elongated housing with a distal end formed of a transparent material (col. 3, lines 3-4) operative to be inserted into a surgical incision and to receive a viewing device and an actuator within its lumen and orient the viewing device to view through

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the distal end of the housing (col. 2, line 67), a tissue spreading dissector mechanism connected to a plurality of flap members which function as tissue spreaders, formed upon the distal end of the housing that is operatively transitional between a first neutral configuration wherein the tissue spreading dissector mechanism extends from the distal end of the housing and an operative configuration wherein the mechanism extends outwardly relative to the distal end of the housing (col. 2, lines 48-53), and an actuator mechanism at the proximal end of the housing, said actuator operatively connected to an actuator within the housing, the actuator mechanism operative to selectively cause the tissue dissecting mechanism and tissue spreaders to selectively transition between neutral and operative configurations (col. 3, lines 13-20).

3. Regarding claim 2, Kan et al further disclose the tissue spreader dissecting mechanism as comprising opposed blade members that extend in diametrically opposed directions from the distal end of the housing when the tissue spreader dissecting mechanism assumes operative configurations (compare figures 1B and 1C).

4. Regarding claims 9 and 10, the dissector that is disclosed by Kan et al is further capable of being axially received within a port and is insertable through a port or a cannula (col. 2, line 67; the device is an elongated tubular shape and therefore is capable of being inserted through a port into a cannula).

5. Regarding claim 11, Kan et al further disclose that the tissue spreader blade members cooperate to define a conical-shaped configuration when assuming the first neutral position (fig. 1A and 1B).

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6. Regarding claims 23 and 31, Kan et al disclose that the distal end of the dissector includes at least 2 or a plurality of flap members formed thereon (col. 4, lines 1-2).
7. Regarding claims 26 and 33, Kan et al further disclose that the housing is a cannula and is tubular (col. 2 line 67; a cannula comprising an elongated hollow tubular object).
8. Regarding claims 27 and 36, the device disclosed by Kan et al is further capable of accommodating a viewing device, such as an endoscope (col. 1, lines 49-52).
9. Regarding claim 32, Kan et al disclose scoop-shaped, which is curved, also known as arcuate, blade members ([11], [12]).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 3-5, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kan et al (US 6,497,651) in view of Privitera et al (US 5,569,291).
12. Regarding claims 3, 4, and 37, Kan et al disclose the invention substantially as claimed except for failing to disclose a clamp mechanism formed on the proximal end of the housing for securely holding the viewing device into position within the lumen of the dissector. However, Privitera et al teach a clamp mechanism on the proximal end of the

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housing (col. 6, lines 17-25) that securely holds a viewing device into position within the lumen. This allows the surgeon better maneuverability, as he or she will not have to worry about holding the viewing device in place with one of his or her hands while using the instrument. Therefore, it would have been obvious to place a clamp on the proximal portion of the housing.

13. Regarding claim 5, Kan et al disclose the invention substantially as claimed except for failing to disclose a stop member within the lumen to limit the distance an endoscope or other viewing device can extend distally within the tubular housing. However, Privitera et al teach a device where the endoscope ends in an abutting relationship with the penetrating tip at the distal end of the shaft (col. 6, lines 17-21). This abutment acts as the stop member. A stop member prevents the viewing device from being inserted too far into the body cavity, thus reducing trauma and injury to the patient. Therefore it would have been obvious to have a stop member within the lumen.

14. Claims 7, 21, 22, 34, 35, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kan et al (US 6,497,651) in view of Wilk (US 5,511,564).

15. Regarding claim 7, Kan et al disclose the invention substantially as claimed except for failing to disclose the following, which is taught by Wilk. Wilk teaches a first pair of arms (136 a and b) pivotally mounted to an actuator rod (134) and a second pair of arms (138, 140) coupled to the first pair that operate to pivot outwardly relative to the first pair, the second pair of arms having tissue spreader members formed on their ends that operate to transition from neutral and operative configurations as the first and second pairs of arms pivotally move relative to one another (col. 11, lines 39-52). This

mechanism of actuating the tissue spreading members is a simple mechanical actuation and is unlikely to cause complications regarding the operation of the device. Therefore it would have been obvious to have a pair of arms pivotally mounted to the actuator rod and also connected to a second pair of arms from which the tissue spreading members extend.

16. Regarding claims 21, 22, 34, and 39, Kan et al fail to disclose a locking mechanism on the actuator mechanism that causes the flap members to assume an operative configuration, and also fail to disclose a lever as the tissue spreading mechanism. However, Wilk teaches a locking mechanism formed upon the actuator mechanism of the port that causes the device to be locked into a neutral and an extended use position (col. 8, lines 7-10). Wilk also teaches a lever as the tissue spreading mechanism (fig. 11 136b and 140). As the first arm (136b) is pushed downward, it provides a force against the second arm (140), pushing the second arm out. This application of force works by the same concept that a lever can be used to move something. By using a lever mechanism, the tissue spreading members can be forced apart relatively easily, and make the device easier to use for surgeons. By using this same locking device to cause the flap members to assume an operative, or extended, configuration, the tissue can be held in a distended position to provide the surgeon with a better field of vision of the area of interest within the body. Therefore it would have been obvious to have a locking mechanism to hold the device in the operative configuration and to use a lever as the tissue spreading mechanism.

17. Due to lack of criticality in the specification, regarding claim 35, a tissue

spreading mechanism comprising a ramp was shown to solve no particular problem, serve no particular purpose and provide no additional benefit as opposed to a tissue spreading mechanism comprising a lever. Therefore, it would have been obvious to have a ramp as the tissue spreading member mechanism because it is capable of working equally as well as a lever tissue spreading mechanism.

18. Claims 6, 14, 40, and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kan et al (US 6,497,651) in view of Yoon (US 5,843,017).

19. Regarding claim 6, Kan et al disclose the invention substantially as claimed except for failing to disclose that the actuator bar is operatively coupled to handle members. However, Yoon teaches handle members that an actuator rod is coupled to, thus causing the movement of the tissue spreading members to move from one position to another (fig. 1, [62] and [64]). Having handle members allows the surgeon to have control of the primary features of the device. Therefore it would have been obvious to have handle members such as those taught by Yoon connected to an actuator rod.

20. Regarding claims 14, 40, and 41, Kan et al disclose the invention substantially as claimed but fail to disclose tissue spreaders in electrical communication with a current source for cauterizing tissue. However, Yoon teaches a tissue dissecting instrument wherein there is a connector device to connect the device to an electrical current source so that the distal ends of the device can be used for cauterization (col. 9, lines 27-32). A device of this size that is used for cauterization is also capable of cauterizing tissue from a blood vessel. Having an eletrocautery capability on the device of Kan et al will enhance the surgeon's ability to correctly perform surgery because it reduces the total

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number of tools and incisions needed to perform the surgery, and reduces blood loss.

Therefore it would have been obvious to supply the device of Kan et al with the ability to cauterize tissue.

21. Claims 8, 20, and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kan et al (US 6,497,651) in view of Ko (US 5,354,302).

22. Regarding claims 8 and 38, Kan et al disclose the invention substantially as claimed except for failing to disclose a channel for administering an insufflative gas to be supplied to a body cavity. However, Ko teaches a channel specifically for the insufflation of gas (col. 6, lines 408). This allows the cavity created by the tissue expanding flaps to be held open by pressure and would also allow therapeutic substances to be introduced into the body cavity. Therefore it would have been obvious to have a channel for gas insufflation as a part of the device.

23. Regarding claim 20, Kan et al disclose the invention substantially as claimed except for failing to disclose an elongated cylindrical sleeve as the actuator. However, Ko teaches an elongated cylindrical sleeve as the actuator of the tissue spreading members such that the distal end of the sleeve causes the tissue spreading members to transition from a closed configuration to an operative configuration (note the difference in the position of the inner tubular member in figures 7 and 8, as well as the difference in position of the distal tissue spreading members). This actuator design provides more structural support to the device than having separate actuator members as in the device of Kan. Therefore it would have been obvious to use a sleeve shaped actuator in this device.

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24. Claims 12, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kan et al (US 6,497,651) in view of Brown et al (US 5,201,752).

25. Kan et al disclose the invention substantially as claimed but fail to disclose a sharpened gripping surface comprising serrated cutting edges on the tissue spreading blade members. However, Brown et al teach blade members with serrated edges (fig. 9, [35]). These edges allow for better gripping of the tissue while it is being held in the distracted position. This reduces the chance that the surgeon will have to reposition the device, and thus reduces trauma to the tissue. Therefore it would have been obvious to have sharpened gripping, or serrated edges on the tissue spreading members.

26. Claims 13 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kan et al (US 6,497,651) in view of Erb et al (US 6,436,119).

27. Regarding claim 13, Kan et al disclose the invention substantially as claimed except for failing to disclose at least one channel-defining void on the tissue-spreading members. However, Erb et al teach a void on the distal ends of the tissue spreading members, through which a viewing device can view the distal end of the housing (fig. 2B). This allows the viewing device to look past the distal end of the instrument and can also allow insertion of other tools to pass through the distal end of the instrument even before the tissue spreading members have been radially expanded. Therefore it would have been obvious to have a channel-defining void on the tissue spreading blade members.

28. Regarding claim 28, Kan et al disclose the invention substantially as claimed except for failing to disclose an increased sidewall thickness of the flap members from

their proximal to their distal ends. However, Erb et al discloses tissue dilating members similar to the flap members that have an increased thickness at their distal ends than the proximal and middle portions of the members (fig. 2A, compare tissue-spreading members' distal end near [78] with proximal end near [70]). This allows greater stability of the tissue spreading members when in the active configuration. Therefore it would have been obvious to increase the sidewall thickness of the tissue spreading members.

29. Claims 16, 17, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kan et al (US 6,497,651) in view of Yoon (US 5,843,017) and further in view of Makover et al (US 5,683,349).

30. Kan et al disclose the invention substantially as claimed except for failing to disclose a metal reinforcement consisting of leaf-spring members to bias the tissue spreading members to a closed configuration. However, Yoon teaches a leaf spring that ultimately functions to keep the tissue spreading members in a neutral closed configuration (col. 8, lines 56-65; when the handles are apart, the tissue-spreading members are in the closed configuration). Yoon also teaches that this device can be made of any medically suitable material (col. 8 line 59).

31. Yoon fails to teach the leaf spring located within the flap members. However, Makover et al teach a spring member located within the tissue-grasping members that biases the members towards the closed position (col. 6, lines 9-12 and lines 31-33). Placing the leaf spring in the proximal end of the device provides no particular advantage over placing it in the distal end of the device. Further, placing the leaf spring in the distal end so as to be a metal reinforcement of the tissue-spreading members

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allows the device to be maintained in its closed configuration with less tension stored in the device, which makes the device safer to use for the surgeon and the patient.

Therefore it would have been obvious to have the leaf spring mechanism as a part of the metal reinforcement of the tissue-spreading members.

32. Claims 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kan et al (US 6,497,651) in view of Pena (US 5,178,133).

33. Kan et al disclose the inventions substantially as claimed except for failing to disclose an elastic sheath. However, Pena teaches an elastic sheath formed radially about a plurality of tissue-spreading members that forms a covering about the opening at this distal end when the tissue spreading members are in their operative configuration and also biases the tissue spreading members towards the closed configuration (). This elastic sheath provides protection of the endoscopic tools from the tissue surrounding the body cavity and also ensures that the tissue spreading members do not expand too far. Therefore it would have been obvious to have an elastic membrane-like sheath covering the tissue spreading members at the distal end of the device.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda Adams whose telephone number is (571) 272-5577. The examiner can normally be reached on M-F, 8:00am-5:00pm, alternate Fridays off.


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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